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10/582,529

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Jin-Woo Lee

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FOLEY & LARDNER LLP  
111 HUNTINGTON AVENUE  
26TH FLOOR  
BOSTON, MA 02199-7610

EXAMINER

RUFO, LOUIS J

ART UNIT

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1759

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/582,529	<b>Applicant(s)</b> LEE, JIN-WOO	
	<b>Examiner</b> LOUIS RUFO	<b>Art Unit</b> 1759	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 12 May 2011.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,6-11 and 15-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,6-11 and 15-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 June 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Species II in the reply filed on 12 May 2011 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### ***Priority***

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Information Disclosure Statement***

3. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### ***Drawings***

4. The drawings are objected to because the labels for each drawing (e.g. Fig. 1, Fig. 2a, Fig. 2b etc.) do not correspond with the written description of the drawings starting on pg. 3 line

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17 of the instant specification which results in no drawing corresponding to Fig. 10-18.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

5. Figure 1, 2, and 3 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled “Replacement Sheet” in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 1, 2, 6-9, and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 1 recites the limitation "first substrate piece" in line 5. There is insufficient antecedent basis for this limitation in the claim. It is unclear to whether a first substrate piece is an equivalent to an "individual reaction element," as they are both formed upon cutting of the first substrate piece.

9. Claim 10 recites the limitation "first and second substrate pieces" in lines 8. There is insufficient antecedent basis for this limitation in the claim. It is unclear to whether a first or second substrate pieces is an equivalent to an "individual reaction element," as they are both formed upon cutting of the first or second substrate pieces, respectively.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

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subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1, 2, 6, 7, 10, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Bergkuist et al (US 6,123,820).

As to claim 1, Bergkuist discloses forming a plurality of reaction elements (Fig. 11 #31-1) applying an assay reagent (col. 6 lines 23-43 and col. 8 lines 33-43) on a first substrate (Fig. 11 #31), cutting into separate reaction elements (col. 10 lines 1-13) and attached to a predetermined portion of a second substrate (Fig. 2 #12A and 12B OR #14 and col. 10 lines 1-13) having more than one capillary for feeding biomaterial through (Fig. 2 #CT1 and CT2 col. 5 lines 3-13).

As to claim 2, Bergkuist discloses attaching a plurality of first substrate pieces to the second substrate (Fig. 11 #'s 31-1 and 30-1 and col. 7 lines 32-36).

As to claim 6, Bergkuist discloses the second substrate is made of plastics (col. 4 lines 25-27).

As to claim 7, Bergkuist discloses forming at least 2 first electrodes on a first side of the first substrate (Fig. 7 and 8 #'s 34a and col. 6 lines 38-39) and applying an assay reagent through each (col. 6 lines 23-43 and col. 8 lines 33-43)

As to claim 10, Bergkuist discloses forming a plurality of reaction elements (Fig. 1 #31-1) applying an assay reagent (col. 6 lines 23-43 and col. 8 lines 33-43) on a first substrate (Fig. 11 #31), forming a plurality of reaction elements (Fig. 1 #31-1) applying an assay reagent (col. 6 lines 23-43 and col. 8 lines 33-43) on a second substrate (Fig. 11 #31, )cutting each separate substrate into separate reaction elements (col. 10 lines 1-13) and attached to a predetermined portion of a third substrate (Fig. 2 #12A and 12B OR #14 and col. 10 lines 1-13) having more than one capillary for feeding biomaterial through (Fig. 2 #CT1 and CT2 col. 5 lines 3-13).

12. Claim 1, 2, 6, 7, 8, 11, 15, 16, and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Wang et al (US 2006/0064035 A1).

As to claim 1, Wang discloses a method of producing a biomaterial measuring device that uses and electrochemical assay comprising:

a first substrate (see Fig. 21 #502) in which an assay reagent is applied (Fig. 21 #506) which is then cut to form an individual reaction element (Karinka et al US 2004/0067166 A1 pg. 9 [0082] incorporated by reference in Wang pg. 9 [0101])

attaching a first reaction element (Fig. 7 #130) to a predetermined portion (Fig. 7 #140) of a second substrate (Fig. 7 #128) with more than one capillary for feeding biomaterial through (Fig. 7 and 8 #150 and pg.6 [0068]).

As to claim 2, Wand discloses a plurality of first substrate pieces are attached to the second substrate (See multiple #130's in Fig. 7).

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As to claim 6, Wang discloses the second substrate to be made of plastics (pg. 4 [0058]).

As to claim 7, Wang discloses two electrodes formed on the first side of the substrate (Fig. 21 #520, 524, or 528) where an assay reagent is applied throughout the first electrodes (pg.10 [0110] lines 12-13).

As to claim 8, Wang discloses a second electrode (Fig. 20 #520 or 524 depending on which side is chosen to be the first) on the opposite side of a first electrode and electrically connecting them when the sample is introduced into they system and a measurement is carried out or through the reagent layer (pg. 10 [0110-0111]).

As to claim11, Wang discloses a first substrate (see Fig. 21 #502) in which an assay reagent is applied (Fig. 21 #506) which is then mounted to a second substrate (Fig. 21 #516) to form capillaries for introducing a biomaterial through (Fig. 21 #515 and 522 leading to 2 intersecting flow channels as shown in the exploded figure).

As to claim 15, Wang discloses the second substrate to be made of plastics (pg. 4 [0058]).

As to claim 16, Wang discloses two electrodes formed on the first side of the substrate (Fig. 21 #520, 524, or 528) where an assay reagent is applied throughout the first electrodes (pg.10 [0110] lines 12-13).



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As to claim 17, Wang discloses a second electrode (Fig. 20 #520 or 524 depending on which side is chosen to be the first) on the opposite side of a first electrode and electrically connecting them when the sample is introduced into they system and a measurement is carried out or through the reagent layer (pg. 10 [0110-0111]).

### ***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bergkuist et al US 6,123,820) in view of Musho et al (US 2003/0201175 A1).

The discussion of Bergkuist as applied to instant Claims 1 and 7 are herein repeated.

Bergkuist fails to disclose forming a second electrode on a second side of the first substrate and electrically connecting at least one of the first electrodes on the first side to the electrode on the second side.

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Musho discloses a first substrate (Fig. 3 #1), an assay reagent applies to the entire first side of the substrate to form a reaction element (pg. 3 [0027]), and a second substrate that the first substrate is mounted on to form capillaries to introducing biomaterial through (pg. 2 [0017] and pg. 4 [0033]), at least 2 first electrodes formed on the first side of the first substrate (Fig. 3 #'s 11) with the assay reagent applies throughout the first electrodes (pg. 3 [0027]), and a second electrode on the second side (Fig. 3 #9) opposite to the first side, which is electrically connected to at least one of the first electrodes (Fig. 3 #11) on the first side through a hole, which is coated with a conductor (pg. 3 [0031]).

Bergkuist and Musho are of analogous art because they are from the same field of endeavor of electrochemical biosensors.

At the time of invention, it would have been obvious to one with ordinary skill in the art to manufacture the first substrate of Bergkuist to include the features of a second electrode on the second side of the first substrate that is electrically connected to the first electrode on the first side of the first substrate as described by Musho to use in biomaterial measuring device. The motivation for doing so would have been to provide electrical leads in the same direction and side of the surface (Musho pg. 3 [0031] and Fig. #2).

16. Claims 9 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al (US 2006/0064035 A1) in view of Matzinger (US 2003/0200644 A1).

The discussions of Wang as applied to claims 1 and 11 are herein repeated.

Wang fails disclose the use of a dehumidifying agent.

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Matzinger discloses the incorporation of a dehumidifying agent in a predetermined portion (Abstract).

Wang and Matzinger are of analogous art because they are of the same field of endeavor of electrochemical sensors.

At the time of invention, it would have been obvious to one with ordinary skill in the art to modify the substrate of Wang to include a dehumidifying agent in a predetermined portion as described by Matzinger. The motivation for doing so would have been to prevent reagent degradation due to water moisture (Matzinger pg. 1 [0005]).

17. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bergkuist et al US 6,123,820) in view of Matzinger (US 2003/0200644 A1).

The discussions of Bergkuist as applied to claim 1 are herein repeated.

Bergkuist fails disclose the use of a dehumidifying agent as well as the composition of a housing.

Matzinger discloses the incorporation of a dehumidifying agent in a predetermined portion (Abstract).

Bergkuist and Matzinger are of analogous art because they are of the same field of endeavor of electrochemical sensors.

At the time of invention, it would have been obvious to one with ordinary skill in the art to modify the substrate of Bergkuist to include a dehumidifying agent in a predetermined portion

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as described by Matzinger. The motivation for doing so would have been to prevent reagent degradation due to water moisture (Matzinger pg. 1 [0005]).

18. Claims 11, and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Musho et al (US 2003/0201175 A1) in view of Karinka et al (US 2004/0067166 A1).

As to claim 11, Musho discloses a first substrate (Fig. 3 #1), an assay reagent applies to the entire first side of the substrate to form a reaction element (pg. 3 [0027]), and a second substrate that the first substrate is mounted on to form capillaries to introducing biomaterial through (pg. 2 [0017] and pg. 4 [0033]).

Musho fails to disclose the explicit forming of capillaries when the two substrates are joined together.

Karinka discloses an electrochemical sensor comprising a base (Fig. 1 #102), a cover (Fig. 1 #116) and capillary flow channels (Fig. 1 #114 ) formed between spacer layers (Fig. 1 #112). When the cover is applied, the capillary channels are formed to introduce biomaterial to the measuring device (pg. 1 [0016], pg. 5 [0054] lines 15-17, and pg. 6 [0061]).

Musho and Karinka are of analogous art because they are both of the same field of endeavor of electrochemical glucose biosensors.

At the time of invention, it would have been obvious to one with ordinary skill in the art to modify the housing of Musho to include the capillary channels that are formed between the housing and the base of Karinka. The motivation for doing so would have been to allow the sample to be drawn in by capillary action (Karinka pg. 1 [0016]) to the capillary sized through-holes of Musho (pg. 2 [0016]).

As to claim 15, Karinka discloses the second substrate (cover) to be made of plastic (pg. 6 [0061]).

As to claim 16, Musho discloses at least 2 first electrodes formed on the first side of the first substrate (Fig. 3 #'s 11) with the assay reagent applies throughout the first electrodes (pg. 3 [0027]).

As to claim 17 and 18, Musho discloses a second electrode on the second side (Fig. 3 #9) opposite to the first side, which is electrically connected to at least one of the first electrodes (Fig. 3 #11) on the first side through a hole, which is coated with a conductor (pg. 3 [0031]).

19. Claims 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Musho et al (US 2003/0201175 A1) in view of Matzinger (US 2003/0200644 A1).

The discussions of Musho as applied to claim 11 are herein repeated.

Musho fails disclose the use of a dehumidifying agent as well as the composition of a housing.

Matzinger discloses the incorporation of a dehumidifying agent in a predetermined portion (Abstract).

Musho and Matzinger are of analogous art because they are of the same field of endeavor of electrochemical sensors.

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At the time of invention, it would have been obvious to one with ordinary skill in the art to modify the substrate of Musho to include a dehumidifying agent in a predetermined portion as described by Matzinger. The motivation for doing so would have been to prevent reagent degradation due to water moisture (Matzinger pg. 1 [0005]).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LOUIS RUFO whose telephone number is (571)270-7716. The examiner can normally be reached on Monday through Thursday 9:30 AM to 3:30 pm and every other Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey T. Barton can be reached on 571-272-1307. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. R./

Examiner, Art Unit 1759

/Jeffrey T Barton/

Supervisory Patent Examiner, Art Unit 1759

9 June 2011